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(12) **United States Patent**
Dorn

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(54) **CATHETER DELIVERY DEVICE**

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CPC ***A61F 2/95*** (2013.01); ***A61F 2/962*** (2013.01); *A61M 25/0052* (2013.01)

(58) **Field of Classification Search**
CPC .. A61F 2/95; A61F 2/962; A61F 2/966; A61F 2/9661; A61F 2/9662; A61F 2002/9665; A61M 25/0052
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,642,068 A 2/1972 Fitch et al.
4,719,853 A 1/1988 Bowers
(Continued)

FOREIGN PATENT DOCUMENTS

CA 2202870 A1 5/1996
DE 3019995 A1 12/1981
(Continued)

OTHER PUBLICATIONS

CA 3,050,184 filed Jun. 10, 2009, Notice of Application found Allowable dated May 20, 2021.
(Continued)

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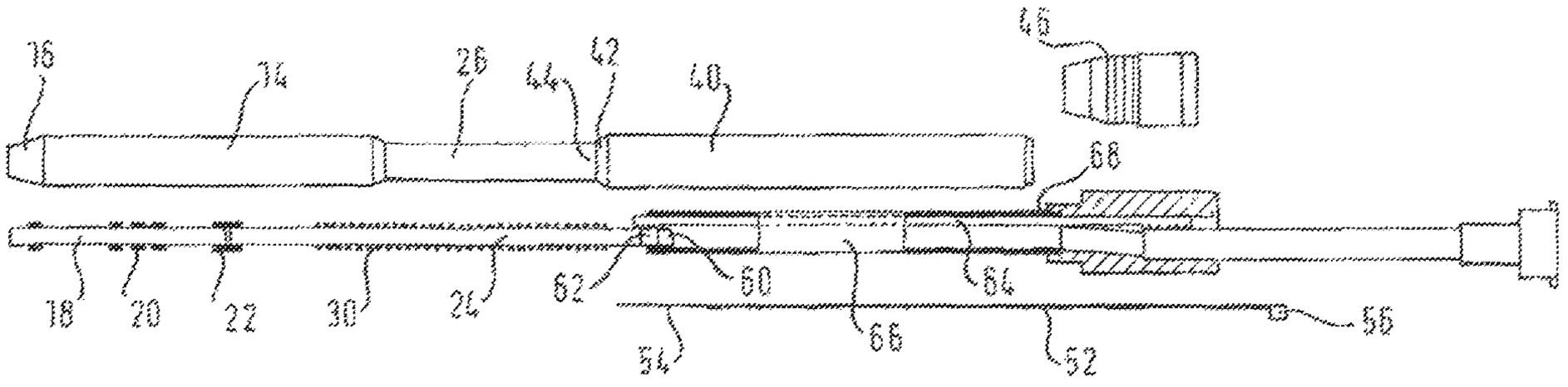
(57) **ABSTRACT**

A catheter delivery device for a self-expanding stent is described. The delivery device includes a distal catheter component and a distal sheath that releases the stent by moving proximally relative to the distal catheter component and the stent. A proximal catheter shaft including a tube and a pull wire within a lumen of the tube may be provided, the pull wire being attached to the distal sheath such that pulling the pull wire proximally relative to the tube pulls the distal sheath proximally to release the stent progressively. A casing tube may be provided to surround the catheter shaft, the casing tube having a distal end that receives telescopically a proximal end of the distal sheath. A method of making a delivery device for implantation of a self-expanding stent is also described.

13 Claims, 2 Drawing Sheets



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(56) **References Cited**

U.S. PATENT DOCUMENTS

5,120,323	A	6/1992	Shockey et al.
5,159,937	A	11/1992	Tremulis
5,246,008	A	9/1993	Mueller
5,456,665	A	10/1995	Postell et al.
5,474,563	A	12/1995	Myler et al.
5,484,425	A	1/1996	Fischell et al.
5,484,444	A	1/1996	Braunschweiler et al.
5,507,766	A	4/1996	Kugo et al.
5,533,987	A	7/1996	Pray et al.
5,573,520	A	11/1996	Schwartz et al.
5,591,194	A	1/1997	Berthiaume
5,628,754	A	5/1997	Shevlin et al.
5,649,908	A	7/1997	Itoh
5,676,659	A	10/1997	McGurk
5,702,373	A	12/1997	Samson
5,702,418	A	12/1997	Ravenscroft
5,718,159	A	2/1998	Thompson
5,741,429	A	4/1998	Donadio, III et al.
5,772,669	A	6/1998	Vrba
5,951,539	A	9/1999	Nita et al.
5,957,930	A	9/1999	Vrba
5,968,052	A	10/1999	Sullivan, III et al.
6,013,019	A	1/2000	Fischell et al.
6,027,863	A	2/2000	Donadio, III
6,042,588	A	3/2000	Munsinger et al.
6,053,903	A	4/2000	Samson
6,107,004	A	8/2000	Donadio, III
6,254,611	B1	7/2001	Vrba
6,258,080	B1	7/2001	Samson
6,296,622	B1	10/2001	Kurz et al.
6,306,145	B1	10/2001	Leschinsky
6,331,186	B1	12/2001	Wang et al.
6,342,066	B1	1/2002	Toro et al.
6,350,278	B1	2/2002	Lenker et al.
6,352,553	B1	3/2002	van der Burg et al.
6,352,561	B1	3/2002	Leopold et al.
6,355,060	B1	3/2002	Lenker et al.
6,361,555	B1	3/2002	Wilson
6,368,344	B1	4/2002	Fitz
6,371,979	B1	4/2002	Beyar et al.
6,375,676	B1	4/2002	Cox
6,380,457	B1	4/2002	Yurek et al.
6,387,118	B1	5/2002	Hanson
6,391,050	B1	5/2002	Broome
6,391,051	B2	5/2002	Sullivan, III et al.
6,402,760	B1	6/2002	Fedida
6,413,269	B1	7/2002	Bui et al.
6,425,898	B1	7/2002	Wilson et al.
6,432,129	B2	8/2002	DiCaprio
6,443,979	B1	9/2002	Stalker et al.
6,468,298	B1	10/2002	Pelton
6,482,211	B1	11/2002	Choi
6,482,221	B1	11/2002	Hebert et al.
6,488,694	B1	12/2002	Lau et al.
6,505,066	B2	1/2003	Berg et al.
6,514,280	B1	2/2003	Gilson
6,517,547	B1	2/2003	Feeser et al.
6,517,569	B2	2/2003	Mikus et al.
6,520,983	B1	2/2003	Colgan et al.
6,530,947	B1	3/2003	Euteneuer et al.
6,554,841	B1	4/2003	Yang
6,572,643	B1	6/2003	Gharibadeh
6,576,806	B1	6/2003	Slaugh et al.
6,579,297	B2	6/2003	Bicek et al.
6,582,460	B1	6/2003	Cryer
6,592,569	B2	7/2003	Bigus et al.
6,592,617	B2	7/2003	Thompson
6,599,296	B1	7/2003	Gillick et al.
6,599,304	B1	7/2003	Selmon et al.
6,605,109	B2	8/2003	Fiedler
6,607,551	B1	8/2003	Sullivan et al.
6,616,996	B1	9/2003	Keith et al.
6,626,934	B2	9/2003	Blaeser et al.
6,629,981	B2	10/2003	Bui et al.
6,629,992	B2	10/2003	Bigus et al.
6,641,606	B2	11/2003	Ouriel et al.
6,656,212	B2	12/2003	Ravenscroft et al.
6,656,213	B2	12/2003	Solem
6,660,031	B2	12/2003	Tran et al.
6,663,666	B1	12/2003	Quiachon et al.
6,676,666	B2	1/2004	Vrba et al.
6,676,693	B1	1/2004	Belding et al.
6,689,120	B1	2/2004	Gerdts
6,695,862	B2	2/2004	Cox et al.
6,699,274	B2	3/2004	Stinson
6,702,843	B1	3/2004	Brown et al.
6,726,712	B1	4/2004	Raeder-Devens et al.
6,726,714	B2	4/2004	DiCaprio et al.
6,736,839	B2	5/2004	Cummings
6,743,219	B1	6/2004	Dwyer et al.
6,749,627	B2	6/2004	Thompson et al.
6,773,446	B1	8/2004	Dwyer et al.
6,780,199	B2	8/2004	Solar et al.
6,786,918	B1	9/2004	Krivoruchko et al.
6,790,221	B2	9/2004	Monroe et al.
6,827,731	B2	12/2004	Armstrong et al.
6,830,575	B2	12/2004	Stenzel et al.
6,843,802	B1	1/2005	Villalobos et al.
6,849,084	B2	2/2005	Rabkin et al.
6,858,034	B1	2/2005	Hijlkema et al.
6,860,898	B2	3/2005	Stack et al.
6,866,669	B2	3/2005	Buzzard et al.
6,884,259	B2	4/2005	Tran et al.
6,899,727	B2	5/2005	Armstrong et al.
6,926,732	B2	8/2005	Derus et al.
6,939,352	B2	9/2005	Buzzard et al.
6,942,688	B2	9/2005	Bartholf et al.
6,945,989	B1	9/2005	Betelia et al.
7,001,423	B2	2/2006	Euteneuer et al.
7,025,773	B2	4/2006	Gittings et al.
7,052,511	B2	5/2006	Weldon et al.
7,052,513	B2	5/2006	Thompson
7,074,236	B2	7/2006	Rabkin et al.
7,118,005	B2	10/2006	Shimazaki
7,147,657	B2	12/2006	Chiang et al.
7,163,552	B2	1/2007	Diaz
7,172,617	B2	2/2007	Colgan et al.
7,172,618	B2	2/2007	Lupton
7,198,636	B2	4/2007	Cully et al.
7,297,302	B2	11/2007	Berg et al.
7,303,580	B2	12/2007	Parker
7,320,702	B2	1/2008	Hammersmark et al.
7,387,640	B2	6/2008	Cummings
7,454,422	B2	11/2008	Chan et al.
7,455,688	B2	11/2008	Furst et al.
7,462,192	B2	12/2008	Norton et al.
7,468,070	B2	12/2008	Henry et al.
7,517,361	B1	4/2009	Ravenscroft
7,550,001	B2	6/2009	Dorn et al.
7,553,322	B2	6/2009	Dorn et al.
7,717,949	B2	5/2010	Dorn
7,758,624	B2	7/2010	Dorn et al.
7,867,267	B2	1/2011	Sullivan et al.
8,075,606	B2	12/2011	Dorn
8,206,348	B2	6/2012	McDermott et al.
8,652,193	B2	2/2014	Dorn
9,750,625	B2	9/2017	Dorn
2001/0034549	A1	10/2001	Bartholf et al.
2001/0049547	A1	12/2001	Moore
2001/0056299	A1	12/2001	Thompson
2002/0016597	A1	2/2002	Dwyer et al.
2002/0028984	A1	3/2002	Hayakawa et al.
2002/0077691	A1	6/2002	Nachtigall
2002/0128678	A1	9/2002	Petersen
2002/0133127	A1	9/2002	Collins
2002/0133141	A1	9/2002	Sparks et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2003/0050686	A1	3/2003	Raeder-Devens et al.
2003/0055447	A1	3/2003	Lee et al.
2003/0093106	A1	5/2003	Brady et al.
2003/0114911	A1	6/2003	Lupton
2004/0006380	A1	1/2004	Buck et al.
2004/0073293	A1	4/2004	Thompson
2004/0087933	A1	5/2004	Lee et al.
2004/0106977	A1	6/2004	Sullivan et al.
2004/0127912	A1	7/2004	Rabkin et al.
2004/0148009	A1	7/2004	Buzzard et al.
2004/0153049	A1	8/2004	Hewitt et al.
2004/0153137	A1	8/2004	Gaschino et al.
2004/0193180	A1	9/2004	Buzzard et al.
2004/0215229	A1	10/2004	Coyle
2004/0215317	A1	10/2004	Cummings
2004/0230286	A1	11/2004	Moore et al.
2004/0267281	A1	12/2004	Harari et al.
2005/0004515	A1	1/2005	Hart et al.
2005/0004553	A1	1/2005	Douk
2005/0021123	A1	1/2005	Dorn et al.
2005/0027345	A1	2/2005	Horan et al.
2005/0033403	A1	2/2005	Ward et al.
2005/0065590	A1	3/2005	Shelso
2005/0065591	A1	3/2005	Moberg et al.
2005/0080476	A1	4/2005	Gunderson et al.
2005/0090887	A1	4/2005	Pryor
2005/0090890	A1	4/2005	Wu et al.
2005/0165352	A1	7/2005	Henry et al.
2005/0182475	A1	8/2005	Jen et al.
2005/0209671	A1	9/2005	Ton et al.
2005/0209675	A1	9/2005	Ton et al.
2005/0246008	A1	11/2005	Hogendijk et al.
2005/0246010	A1	11/2005	Alexander et al.
2005/0288762	A1	12/2005	Henderson et al.
2006/0004438	A1	1/2006	Alexander et al.
2006/0015168	A1	1/2006	Gunderson
2006/0020321	A1	1/2006	Parker
2006/0030923	A1	2/2006	Gunderson
2006/0041302	A1	2/2006	Malewicz
2006/0058865	A1	3/2006	Case et al.
2006/0074409	A1	4/2006	Schuermann
2006/0074478	A1	4/2006	Feller
2006/0089627	A1	4/2006	Burnett et al.
2006/0095110	A1	5/2006	Moberg et al.
2006/0100687	A1	5/2006	Fahey et al.
2006/0100688	A1	5/2006	Jordan et al.
2006/0106455	A1	5/2006	Furst et al.
2006/0111769	A1	5/2006	Murray
2006/0116752	A1	6/2006	Norton et al.
2006/0184225	A1	8/2006	Pryor
2006/0184227	A1	8/2006	Rust
2006/0190069	A1	8/2006	Baker-Janis et al.
2006/0200221	A1	9/2006	Malewicz
2006/0206189	A1	9/2006	Furst et al.
2006/0224112	A1	10/2006	Lentz
2006/0229697	A1	10/2006	Gerdts et al.
2006/0235502	A1	10/2006	Belluche et al.
2006/0247661	A1	11/2006	Richards et al.
2006/0253184	A1	11/2006	Amplatz
2006/0259118	A1	11/2006	Pal et al.
2006/0259123	A1	11/2006	Dorn
2006/0259124	A1	11/2006	Matsuoka et al.
2006/0271150	A1	11/2006	Andreas et al.
2006/0271151	A1	11/2006	McGarry et al.
2006/0282147	A1	12/2006	Andreas
2006/0282148	A1	12/2006	Hammersmark et al.
2006/0282149	A1	12/2006	Kao
2006/0282152	A1	12/2006	Beyerlein et al.
2006/0282157	A1	12/2006	Hill et al.
2007/0027521	A1	2/2007	Andreas et al.
2007/0027522	A1	2/2007	Chang et al.
2007/0043420	A1	2/2007	Lostetter
2007/0043421	A1	2/2007	Mangiardi et al.
2007/0043726	A1	2/2007	Chan et al.
2007/0043728	A1	2/2007	Chan et al.
2007/0055339	A1	3/2007	George et al.
2007/0055340	A1	3/2007	Pryor
2007/0060910	A1	3/2007	Grandt et al.
2007/0073373	A1	3/2007	Bonsignore
2007/0073379	A1	3/2007	Chang
2007/0073391	A1	3/2007	Bourang et al.
2007/0100412	A1	5/2007	Dwyer et al.
2007/0100413	A1	5/2007	Dwyer et al.
2007/0100421	A1	5/2007	Griffin
2007/0100422	A1	5/2007	Shumer et al.
2007/0106364	A1	5/2007	Buzzard et al.
2007/0118201	A1	5/2007	Pappas et al.
2007/0118207	A1	5/2007	Amplatz et al.
2007/0123971	A1	5/2007	Kennedy et al.
2007/0142892	A1	6/2007	Dave et al.
2007/0168014	A1	7/2007	Jimenez et al.
2007/0179519	A1	8/2007	Huisun
2007/0191864	A1	8/2007	Shumer
2007/0191865	A1	8/2007	Pappas
2007/0198048	A1	8/2007	Behan et al.
2007/0198050	A1	8/2007	Ravenscroft et al.
2007/0198076	A1	8/2007	Hebert et al.
2007/0199360	A1	8/2007	Sarac et al.
2007/0203563	A1	8/2007	Hebert et al.
2007/0208407	A1	9/2007	Gerdts et al.
2007/0213813	A1	9/2007	Von Segesser et al.
2007/0219612	A1	9/2007	Andreas et al.
2007/0219613	A1	9/2007	Kao et al.
2007/0219617	A1	9/2007	Saint
2007/0233224	A1	10/2007	Leynov et al.
2007/0244540	A1	10/2007	Pryor
2007/0250149	A1	10/2007	Von Oepen et al.
2007/0250151	A1	10/2007	Pereira
2007/0255390	A1	11/2007	Ducke et al.
2007/0260301	A1	11/2007	Chuter et al.
2007/0265694	A1	11/2007	Sarac et al.
2007/0270779	A1	11/2007	Jacobs et al.
2007/0270932	A1	11/2007	Headley et al.
2007/0270937	A1	11/2007	Leanna
2007/0293930	A1	12/2007	Wang et al.
2008/0009934	A1	1/2008	Schneider et al.
2008/0033570	A1	2/2008	Blitz et al.
2008/0058722	A1	3/2008	Von Oepen et al.
2008/0065014	A1	3/2008	Von Oepen et al.
2008/0071345	A1	3/2008	Hammersmark et al.
2008/0077223	A1	3/2008	Fischell et al.
2008/0103581	A1	5/2008	Goto
2008/0114435	A1	5/2008	Bowe
2008/0114442	A1	5/2008	Mitchell et al.
2008/0183272	A1	7/2008	Wood et al.
2008/0208310	A1	8/2008	McDermott et al.
2008/0234796	A1	9/2008	Dorn
2008/0255651	A1	10/2008	Dwork
2008/0262590	A1	10/2008	Murray
2008/0275541	A1	11/2008	Furst et al.
2008/0288043	A1	11/2008	Kaufmann et al.
2008/0319524	A1	12/2008	Yachia et al.
2009/0036967	A1	2/2009	Cummings
2009/0054972	A1	2/2009	Norton et al.
2009/0105802	A1	4/2009	Henry et al.
2009/0156998	A1	6/2009	Arana et al.

FOREIGN PATENT DOCUMENTS

DE	3910157	A1	10/1989
EP	0303487	A2	2/1989
EP	0437795	A1	7/1991
EP	0473045	A1	3/1992
EP	0517075	A1	12/1992
EP	0608853	A2	8/1994
EP	0680351	A1	11/1995
EP	0688576	A1	12/1995
EP	0792656	A1	9/1997
EP	0807444	A2	11/1997
EP	0810003	A2	12/1997
EP	0823262	A2	2/1998
EP	0904795	A1	3/1999
EP	1364611	A1	11/2003
EP	1457215	A1	9/2004

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

EP	1656963	A1	5/2006
EP	1709987	A1	10/2006
EP	1747793	A1	1/2007
EP	1834610	A1	9/2007
EP	1852138	A1	11/2007
JP	2006-271565	A	10/2006
JP	2007-175440	A	7/2007
JP	2008-104657	A	5/2008
WO	1993015785	A1	8/1993
WO	1996013228	A1	5/1996
WO	1996036298	A1	11/1996
WO	1997043949	A1	11/1997
WO	1998012988	A1	4/1998
WO	1999015219	A1	4/1999
WO	1999044541	A1	9/1999
WO	1999064098	A1	12/1999
WO	2000012031	A1	3/2000
WO	2001078627	A1	10/2001
WO	2001087180	A2	11/2001
WO	2005053574	A2	6/2005
WO	2005072391	A2	8/2005
WO	2006034008	A2	3/2006
WO	2006127931	A2	11/2006
WO	2006133958	A1	12/2006
WO	2006133959	A1	12/2006
WO	2006133960	A1	12/2006
WO	2007004221	A1	1/2007
WO	2007065420	A1	6/2007
WO	2007076114	A2	7/2007
WO	2007138608	A1	12/2007
WO	2008005666	A1	1/2008
WO	2008036156	A1	3/2008
WO	2008093851	A1	8/2008

OTHER PUBLICATIONS

JP 2011-512895 Office Action dated Mar. 27, 2013.
JP 2011-512895 Office Action dated Mar. 28, 2014.
JP 2011-512895 Office Action dated Oct. 10, 2014.
PCT/EP2009/004199 filed Jun. 10, 2009 International Preliminary Report on Patentability dated Nov. 5, 2010.
PCT/EP2009/004199 filed Jun. 10, 2009 Search Report dated Oct. 19, 2009.
PCT/EP2009/004199 filed Jun. 10, 2009 Written Opinion dated Oct. 19, 2009.
U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Advisory Action dated May 21, 2014.
U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Advisory Action dated Oct. 22, 2012.
U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Final Office Action dated Feb. 27, 2014.
U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Final Office Action dated Jun. 29, 2012.
U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Final Office Action dated Mar. 12, 2015.
U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Non-Final Office Action dated Aug. 15, 2013.
U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Non-Final Office Action dated Dec. 22, 2011.
U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Non-Final Office Action dated Oct. 2, 2014.
U.S. Appl. No. 15/659,496, filed Jul. 25, 2017 Advisory Action dated Jun. 4, 2020.
U.S. Appl. No. 15/659,496, filed Jul. 25, 2017 Final Office Action dated Apr. 1, 2020.
U.S. Appl. No. 15/659,496, filed Jul. 25, 2017 Non-Final Office Action dated Jan. 19, 2021.
U.S. Appl. No. 15/659,496, filed Jul. 25, 2017 Non-Final Office Action dated Sep. 27, 2019.
U.S. Appl. No. 15/659,496, filed Jul. 25, 2017 Notice of Allowance dated Apr. 29, 2021.

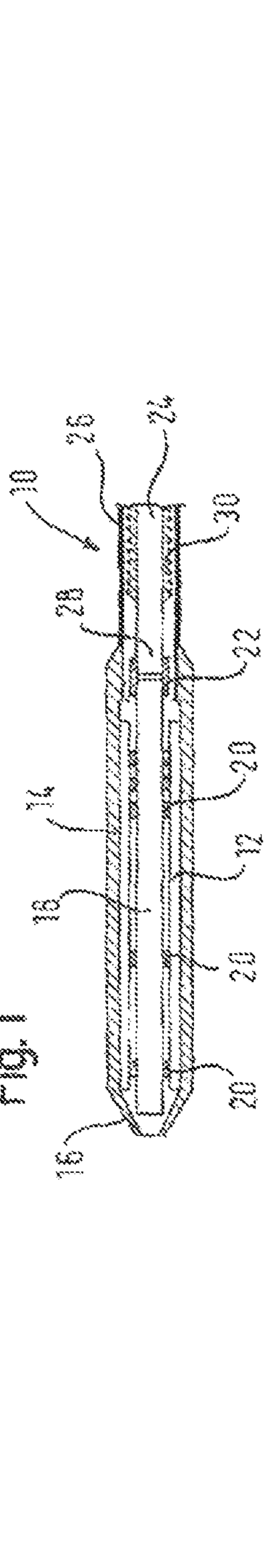

Fig. 1

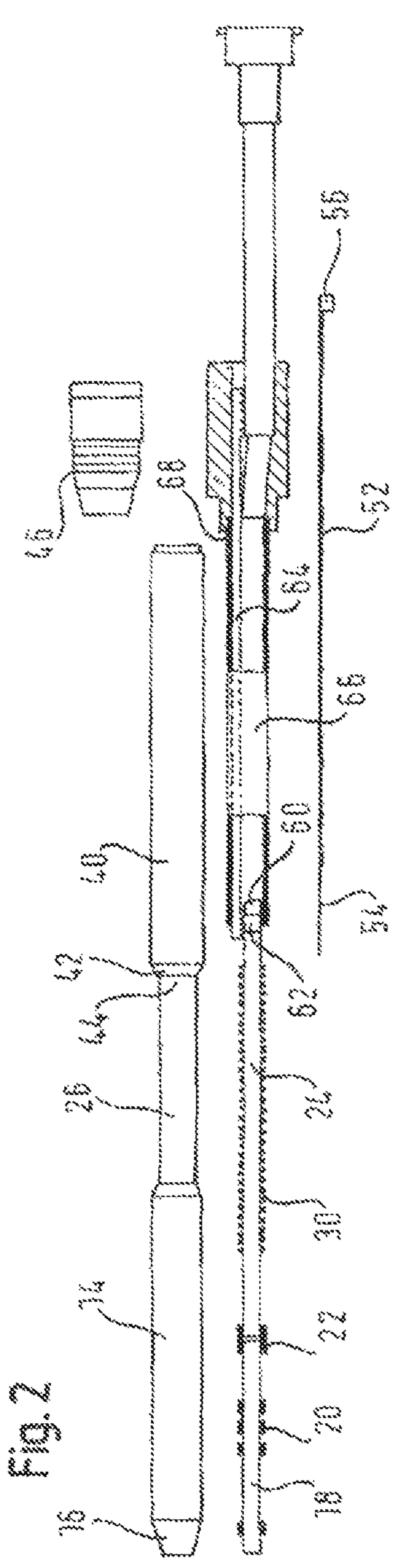

Fig. 2

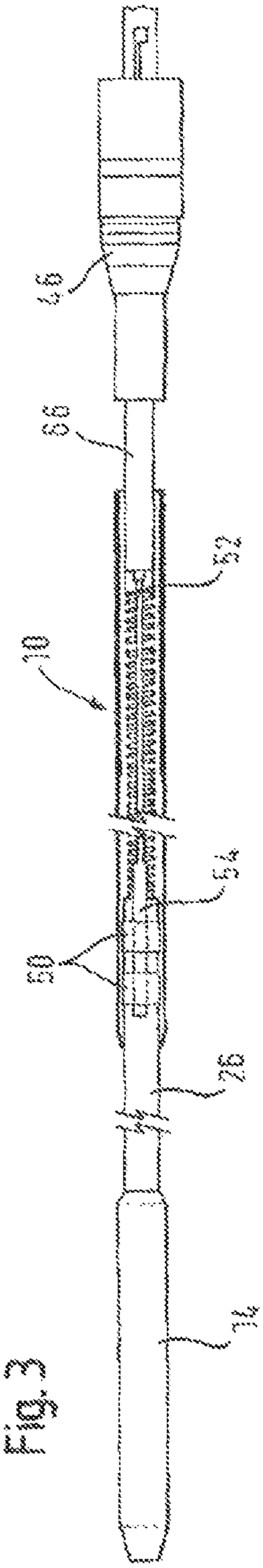

Fig. 3

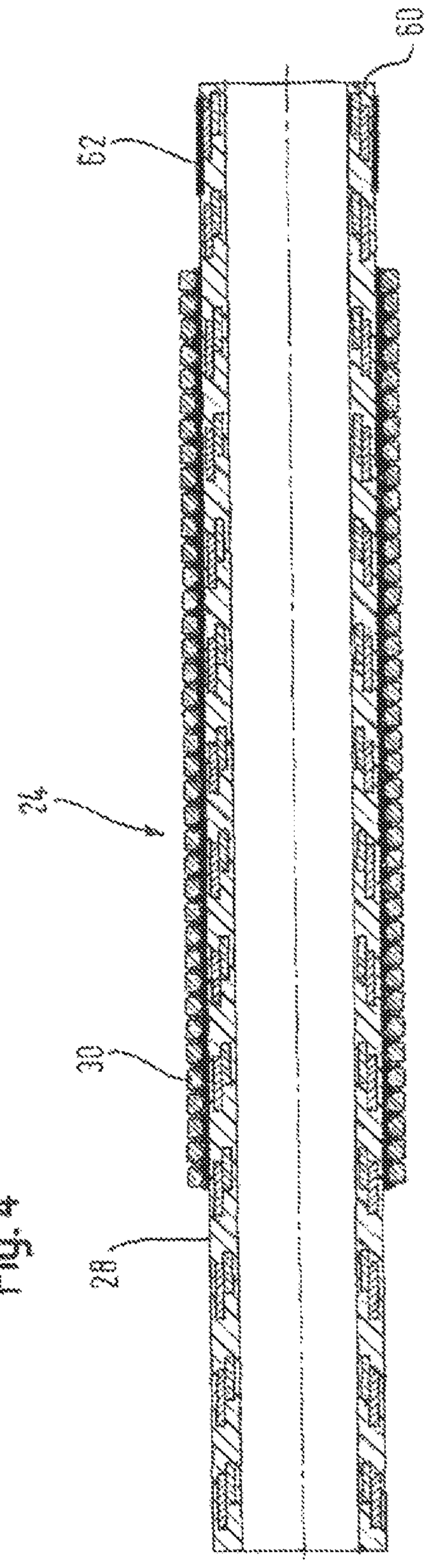

Fig. 4

CATHETER DELIVERY DEVICE

PRIORITY

This application is a continuation of U.S. patent application Ser. No. 15/659,496, filed Jul. 25, 2017, now U.S. Pat. No. 11,109,990, which is a continuation of U.S. patent application Ser. No. 12/481,985, filed Jun. 10, 2009, now U.S. Pat. No. 9,750,625, which claims priority to U.S. Provisional Application No. 61/060,568, filed Jun. 11, 2008, and to United Kingdom Patent Application No. 0810749.2, filed Jun. 11, 2008, each of which is incorporated by reference in its entirety into this application.

TECHNICAL FIELD

This invention relates to a catheter which is a delivery device for a self-expanding stent to be delivered to a stenting location in the body trans-luminally. The device is of the "pull wire" type and is designed for delivery of covered stents of significant length, that represent a tougher delivery task than a short bare stent. The device described below is of the "over the wire" category. However, the present invention can also be applied to "rapid exchange" catheter delivery devices. Guidewire diameters of 18 or 35 "thou" are conventional and contemplated for use with this invention. Covered stents with deployed diameters in a range of from 6 mm to 18 mm are contemplated.

BACKGROUND

The present applicant has progressively developed delivery devices for covered stents. One example is to be found in WO 2005/053574, which is incorporated by reference in its entirety into this application. The present invention carries such architecture forward into the technical field of covered stents that are lengthier (maybe up to 120 mm, or even beyond) and so put greater demands on the strength of the delivery system during deployment of the stent, when a sheath surrounding the stent has to be pulled proximally, relative to the stent, to release the stent into the bodily lumen to be stented, progressively, starting at the distal end of covered stent. Readers will appreciate that it is characteristic of such catheter delivery devices that one of two end-to-end components is in endwise tension (the components responsible for pulling the sheath proximally) while the other of the two end-to-end components (the one that prevents the stent from being drawn proximally with the proximally moving sheath) is in end-to-end compression during progressive deployment of the stent. In general, designers of catheter delivery devices for self-expanding stents try to keep the passing diameter of the catheter to a minimum, which self-evidently conflicts with the design imperative that the end-to-end component in compression does not buckle or concertina, or otherwise lose its length integrity, during stent deployment. The present invention sacrifices ultimate narrowness of passing diameter to the objective of enhanced performance in delivering relatively lengthy covered stents, for which endwise stresses in the catheter delivery device, during deployment of the stent, are likely to be higher than for shorter stents that are bare rather than covered.

Catheter delivery devices that exhibit a "pull wire" are attractive for tasks where the end-to-end stresses are relatively large, because a wire is well able to sustain endwise tension, but not so well adapted to sustain an endwise compressive stress. Better for that task is a tube. Thus, in a coaxial system, one with the tube carrying the compressive stress, and the wire within it carrying the tensile stress, will likely perform better than a system arranged the other way around. However, at the distal end of the system, where the stent is located, it is the outside sheath that is in tension, and the inside catheter element, that stops the stent moving proximally, that is in compression. Thus, somewhere between the proximal and distal end of the catheter delivery system of a pull wire architecture, there needs to be an inversion, to transfer the tensile stress from the radially inner pull wire to the radially outer sheath surrounding the stent. Clearly, any length interval between the transfer zone and the distal end of the stent, in which a relatively small diameter component of the catheter system is required to carry the endwise compressive stress during stent deployment, needs to be strong enough to retain its lengthwise integrity during such stent deployment. Self-evidently, the length of that portion should be reduced, to the extent possible.

A further problem with transfer zones in pull wire systems is to minimize any propensity for the catheter system to buckle at any particular point along its length. Evidently, there is a challenge to incorporate a transfer zone somewhere along the length of the catheter shaft, while at the same time avoiding any points long the length of the catheter where there is an increased risk of buckling.

SUMMARY

Catheter delivery devices in accordance with the present invention can feature novelty in the architecture of the part of the system that withdraws proximally to release the stent. Alternatively, they can exhibit novelty in that part of the system that retains the stent against proximal withdrawal during stent deployment. Preferably the novelty is in both of these component parts of the system, working synergistically together. Each of the contributions to the architecture of the catheter delivery device constitutes an invention in its own right, but the combination of the improved architecture pull back component, with the improved architecture of the component that carries the end-to-end compression during stent deployment, can yield synergistic results that allow the deployment through narrow tortuous lumens, of remarkably lengthy covered stent prostheses.

According to a first aspect of the present invention there is provided a catheter delivery device in which a casing tube surrounds the catheter shaft and has a distal end that receives telescopically a proximal end of the distal sheath of the device, with a pull wire fixed to a proximal end zone of the distal sheath within the lumen of the casing tube.

Normally, the casing tube proximal end is fixed to a hub of an actuating device (otherwise called "hand unit"). Conveniently, the delivery device includes a retaining ring that retains the pull wire on the radially outside surface of a proximal end zone of the distal sheath, the ring embracing the radially outside surface of the distal sheath, near its proximal end. Usefully, the distal end zone of the pull wire is thinned and given the shape of part of a cylindrical surface with a radius that corresponds to that of the radially outer cylindrical surface of the distal sheath near its proximal end, whereby the thinned end zone of the pull wire can lie flush, or close to flush, with a radially outside surface of the distal sheath and, conveniently, clamped to that outside surface by the retaining ring, which is conveniently a swaged ring.

Readers skilled in the art will be able to envisage other ways of extending a sheath into a pull wire. For example, the material of the sheath could itself be continued proximally, to form the pull wire.

In one preferred embodiment, the distal sheath exhibits a diving tube proximal of the location of the stent. The inventor calls this component of the device a "diving" tube because it "dives" into the open distal end of the casing tube and slides proximally within the lumen of the casing tube, during deployment of the stent. The diving tube has an outside diameter slightly smaller than that of more distal portions of the distal portion of the distal sheath, that embrace the stent. Conveniently, the distal end of the diving tube is fixedly received inside the open proximal end of a distal portion of the distal sheath. At the distal end of the distal portion of the distal sheath an inwardly tapered atraumatic tip can be provided, for the catheter device as a whole. Normally, the pull wire will be attached to a zone of the diving tube relatively close to the proximal end of the diving tube, inside the lumen of the casing tube.

Conventionally, in stent delivery systems, an atraumatic tip is provided on an axial component that extends through the lumen of the stent, with the stent sheath terminating proximally of that atraumatic tip. Such arrangements are compatible with the present invention and can provide embodiments of it.

In another aspect of the present invention, the inner catheter component of the delivery device includes a proximal sheath that has a lumen that contains the catheter shaft of the delivery device. It has an open distal end that receives a proximal end of the distal catheter component, side-by-side with the distal end of the catheter shaft. The proximal sheath and the distal catheter component together provide a guidewire lumen that runs the full length of the delivery device, thereby to render the delivery system a member of the "over the wire" type. In one preferred embodiment, the distal end of the catheter tube carries, to one side of the tube axis, a transfer ring that embraces the proximal end of the distal catheter component. We call this ring a "transfer" ring because it marks the transfer of endwise compressive stress during deployment of the stent, between the outer coaxial component constituted by the catheter shaft tube, and the inner coaxial component at the distal end of the delivery device, inside the distal sheath that is pulled proximally to release the stent.

Readers will be able to envisage alternatives to a transfer ring. Depending on the materials of construction of the catheter tube and the distal catheter component, these two components could be joined, side by side, with techniques such as gluing, fusion welding, strapping together or brazing, as well as form-fitting and other ways of achieving a mechanical interference that resists axial shortening.

As mentioned above, the catheter system as a whole must resist any tendency to kink under endwise compression. Transition zones are particularly vulnerable to unwanted kinking. It may therefore be worthwhile to install at the side by side component transfer zone an extra splint or sleeve, to enhance resistance to kinking in this zone.

The conventional way to stop a stent from moving proximally during proximal withdrawal of the surrounding sheath in deployment of the stent, is to provide a form of "stop ring" that the proximal end of the stent butts up against, whenever the stent seeks to move proximally. Normally, such an arrangement imposes no undue compressive stresses on any part of the stent matrix. However, in a case where the stent might be vulnerable to excessive end-to-end compressive stress, a better arrangement is to give the stent cylinder a measure of support, against proximal movement, over a greater part of the length of the stent than just the proximal end surface of the stent cylinder. Since the catheter delivery device of the present invention is specifically adapted for use with lengthy covered stents, it is advantageous to continue the distal catheter component into a stent support tube that is located, in use, inside the lumen of the stent, and supports the stent around that lumen, against proximal withdrawal relative to the distal catheter component, during proximal withdrawal of the surrounding sheath. In one preferred embodiment, the stent support tube is provided with a plurality of annular cushions that mechanically interfere with the covered luminal surface of the stent radially outside the stent support tube.

The word "cushion" is to be interpreted liberally. For example, a simple spiral protruding radially, to press against the luminal surface of the prosthesis or implant, covered stent or bare stent, can serve the desired purpose. Other arrangements are already within the published patent literature, and becoming more numerous as stent lengths continue to increase. For example, the present applicant has described various arrangements in U.S. Pat. Nos. 8,287,582 and 7,717,949, each of which is incorporated by reference in its entirety into this application.

Applicant has previously developed delivery systems for self-expanding stents in which the distal sheath and stent are free to rotate coaxially, relative to the catheter shaft. While this is still possible to engineer, with the present invention, it is envisaged also to have the stent support tube fixed to the catheter shaft without freedom to rotate thereby fixing (via the stent) the outer sheath against rotation relative to the catheter shaft. With such rotation inhibited, there is no risk that the pull wire can wrap itself around the other catheter shaft component.

The distal catheter component, where it lies proximal of the proximal end of the stent, needs to have enough column strength to resist the compressive stress imposed on it when the stent is being released. A known way to improve the column strength of a catheter component is to wrap it with a helical wire. Accordingly, in one preferred embodiment of the present invention a compound catheter portion of the distal catheter component includes a helix of wire to stiffen the compound catheter portion when the compound catheter portion is in end-to-end compression.

Readers will be well aware of the importance of achieving a high enough resistance to compressive stress, and adequate column strength. Also in this area of design, the patent literature offers the reader a range of alternatives to a helical wire wrapping. Specifically, a tube of metal, for example stainless steel or PHYNOX with a multitude of through wall slits transverse to its length direction, can combine high flexibility with high column strength. For a relevant disclosure, see WO 2006/133960 and EP-A-1656963, each of which is incorporated by reference in its entirety into this application.

In one embodiment (not shown) the proximal end zone of the distal catheter component comprises a length portion that exhibits a multitude of slits with their length direction transverse to the length of the distal catheter component. Such slits can increase the flexibility in bending of the distal catheter component, at least in its proximal end zone. Usefully, the slitted length portion is extended distally towards the location of the proximal end of the stent. The distal extension would normally be all the way to the proximal end of the stent but might be less than all the way, for example, if the distal catheter component exhibits a change of material, from metal to polymer, in a zone located proximally of the proximal end of the stent.

Conveniently, the delivery device includes a connection tube with a lumen that receives, in its distal end, the proximal end of the stent support tube and, in its proximal

open end, the distal end of the compound catheter portion. Adhesive compositions can be used to build the combination of the distal catheter component. The annular cushions on the stent support tube can have other forms, indeed, any suitable form of "embossing" that is capable of resisting relative axial movement of the stent, proximally, relative to the distal catheter component.

It is suggested above that cushions within the lumen of the stent can take over completely from a "pusher" ring that abuts the proximal end of the stent. Nevertheless, a ring to abut the proximal end of the stent can also be provided here. In one embodiment, it assists the cushions. In another embodiment it is deliberately spaced away from the proximal end of the prosthesis, and abuts that proximal end only in the event that the cushions somehow fail to prevent all proximal movement of the prosthesis during its deployment.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, and to show more clearly how the same may carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:

FIG. **1** is a lengthwise diametral section of a distal end portion of a first embodiment of catheter delivery device in accordance with the present invention;

FIG. **2** is a schematic lengthwise diametral section of the delivery device of FIG. **1**, partly exploded to show individual components separately;

FIG. **3** is a longitudinal diametral section, as in FIGS. **1** and **2**, but showing the device in its assembled form; and

FIG. **4** is a longitudinal diametral section through the compound catheter portion.

DETAILED DESCRIPTION

The illustrated delivery system **10** is for delivering a covered stent **12** that can be seen in FIG. **1** compressed inside a distal sheath **14** that has an atraumatic tapered distal tip **16**. The stent being a self-expanding stent, it is pressing on the radially inner cylindrical surface of the outer sheath **14**. Inside the radially compressed stent **12** is a stent support tube **18** that defines a guidewire lumen (not visible in FIG. **1**) and carries on its outer cylindrical surface a plurality of annular cushions **20**. For covered stents with a length of more than 100 mm we propose three such cushions near the proximal end of the stent, one at the distal end of the stent, and one part-way along the length of the stent. For shorter stents, the cushion part-way along the stent is likely not needed. The cushions are made of DYMAX material and each can be of a length along the axis of the stent that is in the area of 2 mm to 4 mm. Depending how the cushions are attached to the support tube **18**, it may be beneficial to provide at the distal end of the tube a safety element, namely some form of a stopper that will stop any annular cushion inadvertently sliding off the distal end of the support tube during deployment of the stent.

In FIG. **1**, the stent support tube **18** has a proximal end that is received within a short connection tube **22**, that also receives the distal end of a compound catheter portion **24** based on a tube of polyimide with braid reinforcement within its annular wall thickness, that is destined to carry a lengthwise compression stress when the distal sheath **14** is pulled proximally away from the stent **12** to release it from the delivery system. What pulls the distal sheath **14** from around the sheath is a proximal portion of the distal sheath which we call a "diving sheath" **26** that has an outside diameter marginally smaller than the inside diameter of the distal sheath **14** and a distal end that is received inside the lumen at the proximal end of the distal sheath **14**, where it is fixed by an adhesive composition. The diving sheath **26** surrounds the compound catheter component, with clearance. We propose that it be of braided polyamide with a wall thickness of 100 μm. In the case of relatively large diameter prosthesis, deliverable with a relatively small diameter catheter shaft, it may be that the inside diameter of the distal sheath **14** is significantly bigger than the outside diameter of the distal end of the driving sheath. In such a case it may be useful to provide an intermediate spacer sleeve between the two components.

The compound catheter component in the lumen of the diving sheath has a polyimide shaft element **28** that defines a guidewire lumen and carries glued on its outer cylindrical surface a helical wind of fine wire **30** which serves to stiffen the tube **28** against bending, without too much loss of bending flexibility, especially when the tube **28** is under endwise compression.

Before leaving FIG. **1**, we draw it to the attention of readers that the distal sheath **14**, without the diving sheath **26**, can serve as a pre-assembly during manufacture of the catheter delivery device, with the stent support tube **18** and stent **12** being inserted into the sheath **14** to constitute the sub-assembly. At a later stage in manufacture, the tube **28** of the compound catheter portion can be connected to the stent support tube **18**, for example, by heat-shrinking the polyamide connection tube **22** around both the tube **28** and the stent support tube **18**, using a PET shrink tube at around 200° C. After such shrinking, the PET tube is removed and discarded. Thereafter, the diving sheath **26** can be introduced into the distal sheath **14** with or without an intervening spacer sleeve, and fixed to it with adhesive.

Turning now to FIG. **2** of the drawings, we see components of the delivery device arranged in an "exploded" form, just enough to separate the components of the inner and outer coaxial members. Thus, the sub-assembly of distal sheath **14** and diving sheath **26** is shown displaced sideways from the stent support tube but coaxial with a casing tube **40** that has a distal end **42** that receives a proximal end **44** of the diving sheath **26**. The proximal end of the casing tube **40** is fixed by adhesive to a strain-relieving hub **46** of a hand unit that will actuate the deployment of the stent from the delivery device. During deployment of the stent, the distal sheath **14** and diving sheath **26** move proximally, but the casing tube **40** does not, so that the proximal end of the diving sheath **26** slides proximally down the lumen of the casing tube **40**, from the open distal end **42**.

We briefly turn to FIG. **3** to complete the description of the proximal movement of the distal sheath. FIG. **3** shows a pair of retaining bands **50** that are swaged into rings around a proximal end zone of the diving sheath **26**. These rings press onto the outer cylindrical surface of the diving sheath **26**, the distal end of a pull wire **52** which has a flattened portion **54** at its distal end that lies underneath the swaged bands **50**, pressed against the surface of the diving sheath **26**. Laser welding is used, to weld the pull wire to the retaining bands **50**. It is tension in the pull wire **52**, imposed from proximal of the proximal end **56** of the pull wire **52**, that pulls the diving sheath, and hence the distal sheath **14**, away from the stent **12**.

Reverting to FIG. **2** of the drawings, we see again the stent support tube **18**, connection tube **22** and compound catheter portion **24**. We also see the proximal end **60** of the tube **28** of the compound catheter portion **24** being held within a transfer ring **62** that is swaged around the proximal end **60**.

That transfer ring is welded to a catheter shaft tube **64** of PHYNOX alloy that defines a lumen that channels the pull wire **52**.

A proximal sheath **66** surrounds the catheter tube **64**, nested, but with the catheter tube **64** away from the rotational axis of the proximal sheath **66**. That leaves most of the cross-section of the lumen of the proximal sheath **66** free for flushing liquids and a guidewire. The guidewire lumen defined by the proximal sheath **66** continues into the lumen of the compound catheter portion and stent support tube. The proximal end **68** of the sheath **66** is set in the same hub **46** as carries the proximal end of the casing tube **40**, so that there is no relative endwise movement between the casing tube **40** and the proximal sheath **66**. Please note that the ratios of diameter to length in FIGS. **2** and **3** of the drawings bears no relation to reality, in which the overall length of the device likely will be substantially more than a 100 cm whereas the passing diameter contemplated is less than 3 mm (7 French or 8 French). It appears from FIG. **2**, for example, that the diving sheath **26** will abut the proximal sheath **66**, at least when the stent is deployed. However, looking at FIG. **3**, we can see a very substantial end-to-end gap between the diving sheath **26** and the distal end of the proximal sheath **66**. The representation in FIG. **3** is misleading as to the length of the proximal sheath **66**. In practice, it occupies a very substantial portion of the total length of the system. The total length of the distal sheath **14**, diving sheath **26** and compound catheter portion **24**, proximally as far as the transfer ring **62**, will be much less than 50% of the total length of the catheter system. In reality, and prior to deployment of the implant, the proximal end of the diving sheath **26** is a considerable distance away, distally, from the distal end of the proximal sheath **66**, as shown in FIG. **3**, but contrary to the impression given by the exploded diagram of FIG. **2**.

For a more detailed description of the compound catheter portion, see the text below, that describes what is shown in FIG. **4** of the drawings.

In operation, the delivery device with its distal end zone looking like it is represented in FIG. **1** is introduced transluminally into the body, and advanced as is known per se, until the distal end is at the location in the body where stenting is desired. At that point, when the stent is to be deployed, the hand unit is actuated, to impose a tensile stress on the pull wire **52**, from its proximal end **56**. This tensile stress passes through to the distal sheath **14**, which moves proximally, with sliding of the diving sheath **26** into the casing tube **40**. The stent **12** would be inclined to be carried proximally with the outer sheath **14**, except that it is prevented from so doing, by the interaction with the inner surfaces of the covered stent by the cushions **20** of the stent support tube **18**. Any tendency of the stent support tube **18** to move proximally with the outer sheath **14** is resisted by compression stress that is generated all the way from the actuation unit along the catheter tube **64**, through the transfer ring **62** and along the compound catheter portion **24**, up to the end-to-end abutment with the stent support tube **18** inside the connection ring **22**, and thence to the cushions **20** and the stent.

After successful deployment of the stent, retraction and removal of the delivery device is relatively straightforward. The cylindrically outside surfaces of the catheter system are generally smooth, and likely anyway to be coated with a lubricious coating. The atraumatic distal tip **16** of the system has stretched to pass proximally over the covered stent but is still residually inwardly tapered during withdrawal of the system. Inside the stent, there is no bulky tip structure that has to pass through the lumen of the stent, from beyond the distal end to proximally of the stent lumen. Instead, the only structure that has to slip proximally out of the stent lumen is that of the stent support tube **18**, which represents a minimal tendency to snag on the inside of the stent.

Turning now to FIG. **4** of the drawings, we find the compound catheter portion **24** shown at a larger scale so that its constructional details can be seen more clearly. The portion **24** is based on a polyimide tube **28** that includes within its annular wall thickness a braid of flat wire. The annular wall thickness is 0.075 mm and the outer diameter is 1.16 mm. The inner diameter is 1.01 mm and the flat braiding wire has a rectangular cross-section of thickness 0.013 mm and width of 0.076 mm. The braid is based on SS304W steel material, braided at 100 PPI (crossing points per inch). There are 16 wire bands altogether in the braid.

Turning now to the helical wind of multi-strand wire on the outer cylindrical surface of the polyimide tube **28**, this is glued to the tube with cyanoacrylate glue and, after wrapping, the outside diameter of the helical coil is 1.5 mm (to a tolerance of 0.02 mm). After mounting on the tube **28**, the helical coil is ground to a final outside diameter of 1.4 mm. As is evident from drawing FIG. **4**, the helical coil does not cover the entire axial length of the compound catheter component. Proximally, it stops short of the transfer ring **62**. Distally, it stops 50 mm short of the distal end of the tube **28**, well short of the connection tube **28** and, as can be seen in drawing FIG. **1**, well short of the proximal end of the sheath **14** which lies radially outside the covered stent **12**.

Variations in the construction of the delivery device shown in the drawings will be evident to those skilled in the art. Materials selection is part of the routine burden of the delivery system designer, as is choice of methods for reliably connecting individual components of the delivery system. A number of individual features of the stent delivery system are known in themselves, but there are multitudes of features routine to use in stent delivery devices that can be mixed and matched to achieve particular requirements of the delivery task to be performed. The number of design considerations to be taken into account is almost infinite. Thus, putting together a synergistic combination of individual components, that permits the delivery of longer covered stents than hitherto, with greater radial stenting force than hitherto, beyond the capability of any delivery system hitherto available, represents a valuable and important contribution to the art.

INDUSTRIAL APPLICABILITY

A catheter delivery device is disclosed, that has a specific architecture capable of delivering through tortuous bodily lumens with a narrow diameter a covered self-expanding stent with a greater length, and higher stenting force, than would hitherto have been possible.

What is claimed is:

1. A method of making a delivery device for implantation of a self-expanding stent, comprising:

preparing an inner delivery component, comprising:

coupling a proximal catheter component to a compound catheter component, wherein a pull wire tube is nested in the proximal catheter component, and wherein a pull wire is positioned in the pull wire tube; and

coupling the compound catheter component to a distal catheter component, the distal catheter component configured to carry the self-expanding stent, wherein the proximal catheter component, the compound

catheter component, and the distal catheter component together define a contiguous guidewire lumen from a proximal end of the inner delivery component to a distal end of the inner delivery component;

preparing an outer delivery component, comprising:

inserting a casing tube into a diving sheath such that relative motion between the casing tube and the diving sheath is permitted; and

securing the diving sheath to a distal sheath;

disposing the outer delivery component over the inner delivery component, wherein the casing tube surrounds the proximal catheter component and the distal sheath surrounds the distal catheter component;

connecting a distal end of the pull wire to the diving sheath; and

attaching the proximal catheter component to a hub.

2. The method according to claim **1**, further comprising fixing a proximal end of the casing tube to the hub.

3. The method according to claim **1**, wherein connecting the distal end of the pull wire to the diving sheath comprises swaging a band around the pull wire and the diving sheath.

4. The method according to claim **1**, wherein the distal end of the pull wire comprises a flattened portion, and wherein connecting the distal end of the pull wire to the diving sheath comprises pressing the flattened portion against an outer surface of the diving sheath.

5. The method according to claim **4**, further comprising laser welding a pair of retaining bands around the flattened portion and the diving sheath.

6. The method according to claim **1**, wherein the distal sheath comprises a distal end tapering radially inwardly to provide an atraumatic tip.

7. The method according to claim **1**, wherein the compound catheter component has a lumen diameter equivalent to a lumen diameter of the distal catheter component, and wherein coupling the compound catheter component to the distal catheter component comprises heat shrinking a polyamide connection tube around the compound catheter component and the distal catheter component.

8. The method according to claim **1**, wherein the compound catheter component comprises a braid reinforcement in an annular wall.

9. The method according to claim **8**, wherein the braid reinforcement includes a helix of flat wire braided at 100 crossing points per inch.

10. The method according to claim **9**, wherein the braid reinforcement comprises 16 wire bands having a rectangular shape.

11. The method according to claim **1**, wherein the distal catheter component includes embossing on an outer surface, the embossing engaging with a luminal surface of the self-expanding stent.

12. The method according to claim **1**, wherein the distal catheter component comprises a length portion including a multitude of slits with a length direction of the multitude of slits transverse to the length portion of the distal catheter component, the length portion with the multitude of slits increasing the flexibility in bending of a proximal end zone of the distal catheter component.

13. The method according to claim **12**, wherein the length portion with the multitude of slits extends to a proximal end of the self-expanding stent.

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